K111283 (1/3)

MAY 27 2011

510(k) Summary

Manufacturer: Medacta International SA
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Date Prepared: May 6, 2011

DEVICE INFORMATION

Trade/Proprietary Name: GMK® Total Knee System - GMK Revision Hybrid Liners
Common Name: Total Knee Prosthesis – Tibial Inserts
Classification Name: Knee joint patellofemorotibial metal/polymer/metal semiconstrained cemented prosthesis

Classification: Class II, 21 CFR 888.3560
Product Code: JWH
Predicate Device: K090988 GMK® Total Knee System (Medacta International), cleared July 10, 2009

Product Description

This modification to the original Medacta GMK® (Global Medacta Knee) Total Knee System is a line extension to include the GMK® Revision Hybrid Liners. The GMK® Revision Hybrid Liners work with tibial baseplates from the GMK® Total Knee System, femoral components from the Evolis Total Knee System, and an extension stem, offset connector, and tibial wedges from the GMK® Total Knee System – Revision, which are optional for patient specific cases. The GMK Revision Hybrid Liners provide the surgeon with an additional option. The GMK® Revision Hybrid Liners are offered as both Ultracongruent (UC) Fixed and Posterior Stabilized (PS) Fixed in six sizes with five thicknesses from 10 mm to 20 mm. The GMK® Revision Hybrid Liners are attached to the GMK® tibial baseplates of the same size from the GMK® Total Knee System and articulate with the existing Evolis femoral component. The device is used primarily during an Evolis Revision surgery where the Evolis tibial baseplate is revised with a GMK tibial baseplate and the existing Evolis femoral component stays intact. The GMK Revision Hybrid Liners can also be used if a surgeon desires to couple a GMK tibial baseplate with an Evolis femoral component during a primary surgery. GMK Revision ultracongruent hybrid liners can be used only with standard Evolis femoral components and fixed GMK tibial baseplates. GMK Revision posterior-stabilized hybrid liners can be used only with posterior-stabilized Evolis femoral components and fixed GMK tibial baseplates.

Indications for Use

The Evolis®/GMK® knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

Comparison to Predicate Devices

The GMK® Total Knee System was cleared under K090988. GMK® Revision components, as a line extension, was cleared under a Special 510(k), K102437. Evolis Total Knee System was cleared under K081023 and was the main predicate for the

GMK Total Knee System. The subject of this submission is the GMK® Revision Hybrid Liners, an additional line extension of the GMK Total Knee System.
The indications for use for the modified system remain the same as the GMK Revision 510(k), K102437.
The GMK® Revision Hybrid Liners are made of Ultra High Molecular Weight Polyethylene (UHMWPE), the same material and processing, as is used in the GMK® Total Knee System's standard, ultracongruent (UC), and posteriorstabilized (PS) tibial inserts and patellas. Like the GMK® Total Knee System's PS tibial inserts, the GMK® Hybrid PS Liners are attached to the GMK® fixed bearing tibial baseplates, cleared in the original GMK® Total Knee System. They are attached with a fixing screw, which is identical to the GMK® PS tibial inserts.
The GMK® Revision Hybrid Liners are offered in thicknesses from 10 to 20mm and in sizes 1 – 6, the same as all of the GMK® Total Knee System components. The GMK® Revision Hybrid Liners only work with the same size GMK® tibial baseplate, similar to how the previously cleared tibial inserts work. The GMK Revision Hybrid Liners may be used with either a left or right GMK® tibial baseplate in the same manner as the previously cleared tibial inserts. The GMK® Revision Hybrid Liners, when attached to the GMK® tibial baseplates, allow the use of extension stems, offset connectors, and tibial wedges as optional augments, identical to the other previously cleared tibial inserts. On the femoral side, the GMK® Revision Hybrid Liners only work with the same size Evolis femoral component. GMK Revision ultracongruent hybrid liners can be used only with standard Evolis femoral components and fixed GMK tibial baseplates. GMK Revision posterior-stabilized hybrid liners can be used only with posterior-stabilized Evolis femoral components and fixed GMK tibial baseplates.

Performance Testing

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act.
The modification to the GMK® Total Knee system to include the addition of the GMK® Revision Hybrid Liners was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device systems. The testing was conducted on the worst case component size and option/design based on engineering analysis. The performance testing conducted on the GMK® Revision Hybrid Liners was very similar to the protocols conducted for the predicate device, the GMK® Total Knee System. The testing included range of motion and mobility of the articulating surfaces, comparative wear behavior, and a measure of the clipping system endurance. The testing met all acceptance criteria and verifies that the performance of the GMK® Revision Hybrid Liners is substantially equivalent to the predicate device systems.

Conclusion:
Based on the above information, the GMK Revision Hybrid Liners can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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MAY 27 2011

Re: K111283
Trade/Device Name: GMK® Total Knee System – GMK Revision Hybrid Liners
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: May 6, 2011
Received: May 6, 2011

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111283 (1/1)

Indications for Use

510(k) Number (if known): K111283

Device Name: GMK® Total Knee System – GMK Revision Hybrid Liners

Indications for Use:

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Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Eric Kuth

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices